NICE advice

Visensia for early detection of deteriorating vital signs in adults in hospital

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Summary

Visensia is physiological monitoring software that collates and analyses data from bedside monitors on 5 vital signs to produce a single patient health status score. This is used for early identification of deterioration that might lead to cardiac or respiratory arrest. One prospective, single-centre, before-and-after study found that patients monitored with Visensia had a statistically significantly shorter average duration of any cardio-respiratory instability and fewer episodes of serious and persistent instability, although changes in patient management may have influenced these findings. The Visensia software requires existing physiological monitors to provide data and costs £1950 for a 1-bed perpetuity licence; individual hospital systems are priced according to size and include installation and configuration charges.

Product summary and likely place in therapy	Effectiveness and safety
• Visensia software analyses data on a patient's heart rate, blood pressure, temperature, oxygen saturations and respiration rate to generate a single numerical score, called the Visensia safety index (VSI). Changes in the VSI indicate whether a patient's vital signs are deteriorating, stable or improving. • Visensia would be used in any hospital setting, where the physiological data are available, to help early identification of deterioration that puts patients at increased risk of cardiac or respiratory arrest.	• One prospective, single-centre, before-and-after study assessed the number and duration of cardio-respiratory instability episodes in potentially unstable patients who had been transferred from intensive care units to step-down units. Of the patients, 306 were monitored with Visensia and 326 had usual ward care. Patients monitored with Visensia had a statistically significantly shorter average duration of any instability, shorter average duration of physiologically significant instability, and fewer episodes of serious and persistent instability. Other instability outcomes, such as the number of admissions experiencing at least 1 episode of instability, were not statistically significantly different between groups. Mortality was recorded for each group but no statistical comparison was made. Changes to patient care introduced during the study may also have contributed to improvements attributed to Visensia. • Another fully published study was a retrospective analysis of a randomised controlled trial in which Visensia was used to record vital signs in high-risk medical and surgical patients. Using the software, abnormal physiological episodes developing into major events, such as cardiac arrest, could be predicted with a sensitivity of 63% and specificity of 52%. Technical problems with the Visensia software prevented recording for the whole monitoring period in 33 (17%) patients.

Technical and patient factors	Cost and resource use
• The Visensia software integrates with standard bedside monitors to collect vital sign data. It reports the data at central nursing stations or medical information systems. • Deterioration in a patient's VSI triggers an audible and visual alarm at the bedside and at the nurses' central station.	• A number of purchasing models are available, including bed licence purchase and leasing via annual or monthly payment arrangements. • The cost for a 1-bed perpetuity licence is £1950. As installations vary in size, individual quotes will be prepared to include installation and configuration charges.

Introduction

The vital signs of acutely ill patients in hospital are monitored so that appropriate care can be given if their condition deteriorates.

Vital signs recorded include:

- heart rate
- respiratory rate
- systolic blood pressure
- level of consciousness
- oxygen saturation
- body temperature.

A retrospective case record review of 1000 adults who died in 2009 in 10 acute hospitals in England judged that 52 of these deaths (5.2%) were preventable (Hogan et al. 2012). The main factor associated with the preventable deaths was clinical monitoring, including: the failure to act upon results of tests or clinical findings; failure to set up and respond to monitoring systems; or failure to increase the intensity of care when needed. The NHS database of patient safety incidents recorded over 2000 preventable deaths in adult NHS patients in England from 1 June 2010 to 31 October 2012 (Donaldson et al. 2014). Again, the main factor associated with these preventable deaths was mismanagement of patient deterioration, which accounted for 35% of

these deaths. Mismanagement included failure to act on or recognise deterioration, failure to give ordered treatment or support in a timely way, and failure to observe patients' vital signs.

Technology overview

This briefing describes the regulated use of the technology for the indication specified, in the setting described, and with any other specific equipment referred to. It is the responsibility of healthcare professionals to check the regulatory status of any intended use of the technology in other indications and settings.

About the technology

CE marking

The Visensia physiological monitoring software (OBS Medical) is a class IIa device for which the manufacturer received a CE mark in November 2010, renewed in January 2015.

Description

The Visensia physiological monitoring system is software that uses a standard Health Level 7 (HL7) interface for communicating to and from other data sources such as bedside monitors, central stations, telemetry kits and electronic patient records. This allows healthcare organisations to use existing patient monitoring and data infrastructures. It was originally marketed under the name BioSign; the change in name was not associated with any changes to the software itself.

Visensia analyses and interprets data from 5 vital signs:

- heart rate
- blood pressure
- temperature
- peripheral oxygen saturation
- respiratory rate.

The vital sign data can be collected automatically and continuously from bedside monitors or taken at periodic intervals. Alternatively the vital sign data can be entered manually into the software. The data are combined to generate a single numerical index called the Visensia safety index (VSI),

which can be displayed at the bedside monitor and at the nurses' central station. The VSI is based on a model of normality derived from a population of high-risk patient groups on a general ward.

The VSI is recalculated and the alert status will update every time new vital sign data are received, continuously or periodically. The VSI ranges from 0 (no abnormalities) to 5 (severe abnormalities):

- A score of less than 1 is considered normal and unlikely to be a cause for concern. However, if a patient has started with a score of 0 and a gradual increase to a score of 1 has been noted, this may merit investigation to see what has changed.
- A score between 1 and 2 is moderately abnormal, and may merit investigation.
- A score between 2 and 3 is indicative of a worsening condition for patients whose score was initially lower.
- Any score above a threshold index of 3 will generate an alert. This is the clinically validated threshold that provides the best sensitivity and specificity for the early identification of deterioration and cannot be changed by users. The alert indicates that a single vital sign has changed by approximately 3 standard deviations from its normal value, or that 2 or more vital signs have changed by a smaller amount. The alert can be sent immediately for patients having periodic monitoring, or after a delay (for example, if the score persists for 4 out of 5 minutes). Staff are notified by an audible and visual alarm at the bedside and at the nurses' central station.

Visensia comprises 2 components, the Server and the Client. The Server has a minimum recommended specification for its use is as follows:

- 2 GHz or better Pentium 4 equivalent processor
- 1 GB or better memory
- 10 GB free disk space
- 100 Mb Ethernet connection.

The Server processes the vital sign data, and using the minimum recommended specification can process information from up to 500 beds. The Server has no graphical user interface; it runs as a service in the Microsoft Windows operating system, calculating the VSI and alert status for each patient as and when new data are received.

The Client has a minimum recommended specification for use as follows:

- 1 GHz or better Pentium 4 equivalent processor
- 512 MB or better memory
- 1 GB free disk space
- 10 Mb Ethernet connection.

The Client component of Visensia is a visual display of the patients being monitored, the patient data received, and the current VSI and alert status. It can be customised to display the beds in each room, ward or floor. The Client display includes the following information for each patient:

- the name of the bed or room being monitored
- the name and ID of the patient being monitored
- each patient's latest VSI
- warning indicators for the bed or room being monitored
- index timestamp showing when the latest VSI was calculated
- trend display of historic index values in graph or table form
- pie chart showing the contribution of each vital sign to the current VSI
- patient trend indicator indicating improvement or deterioration in the VSI over a period of time
- alert status display shown on an alert control button (this is a coloured square which is red if there is a non-silenced alert, gold when the alert has been silenced and green to indicate that the VSI has been calculated and it is neither alerting nor silenced)
- an alert warning border for each patient (this is a coloured border around each patient's VSI, which flashes red to indicate an alert, grey to indicate a technical warning, gold to indicate a silenced alert, or green to indicate a normal state)
- vital signs display showing a list of the current vital signs, values and times each vital sign was recorded for the patient
- observation frequency change, which sets the observation frequency rate for the patient.

The information can also be viewed on a drill-down display. This display includes a list of patients ordered according to the alert status and then the VSI. Selecting an individual patient from the list will show the vital signs and the VSI for that patient.

The Server can have an unlimited number of Client connections, meaning that it can be accessed from different computers around the hospital. When displaying data from several patients, the Client screen can be configured to show the data being received for each patient, their VSI and alert status. It can also be configured simply to provide an overview VSI and alert status of all patients monitored throughout the hospital.

Setting and intended use

The Visensia software is intended to be used by healthcare professionals for routine physiological monitoring of high-risk adult patients who need level 1 and level 2 care on acute hospital wards, to provide an early warning of patient deterioration. Level 1 care includes patients at risk of their condition deteriorating, or those recently relocated from higher levels of care, whose needs can be met on an acute ward with additional advice and support from the critical care team. Level 2 care patients are those needing more detailed observation or intervention including support for a single failing organ system or post-operative care and those 'stepping down' from higher levels of care.

Current NHS options

The NICE guideline on acutely ill patients in hospital recommends that adult patients in acute hospital settings should have physiological observations recorded and a monitoring plan written on admission (or initial assessment). Physiological observations should then be recorded at least every 12 hours, or more often if abnormal parameter values are detected. Multiple-parameter or aggregate weighted scoring systems should include heart rate, respiratory rate, systolic blood pressure, level of consciousness, oxygen saturation and body temperature. This score is increased for any patient needing supplemental oxygen (oxygen delivery by mask or nasal cannulae; Royal College of Physicians 2012).

NICE is aware of the following CE-marked devices that appear to fulfil a similar function to the Visensia monitoring system:

- IntelliVue Guardian EWS (Philips).
- Nervecentre (Nervecentre Software).
- VitalPAC (The Learning Clinic).

- Wardware (Airslie).

Costs and use of the technology

The cost of the Visensia software varies because it is tailored to meet the needs of each hospital. A number of purchasing models are available, including bed licence purchase and leasing via annual or monthly payment arrangements. The price for a 1-bed perpetuity licence is £1950. As installations vary in size, individual quotes will be prepared to include installation and configuration charges. Maintenance and support is charged annually and is based on the number of beds licensed at the point of renewal. As a guide, for a 24-bed level 1 facility there would be a £40,000 initial licence cost with an ongoing software service and support contract. For a 12-bed level 2 facility, there would be an initial cost of £22,000 plus the software service and support contract. There is also a 1-time installation charge which is generally around £2500. The software service and support contract is an annual fee calculated at 15% of the initial licence purchase. This would be £6000 per year for a 24-bed facility and £3300 for a 12-bed facility. This is payable for the period that Visensia is being used in the hospital.

Likely place in therapy

The Visensia software would be used as an adjunct to existing vital signs monitors and provide additional information as an aid to clinician decision making.

Specialist commentator comments

One specialist commentator noted that patients in high-dependency units generally have a higher level of care than that normally provided on the wards; these patients are usually in the unit because deterioration (or the potential for it) has already been recognised. For this reason, the commentator felt that the software would be more useful in wards not necessarily designated or funded as high-dependency unit areas, but where care is provided for patients who are considered to be high risk or level 1 to 2.

Another specialist commentator considered that the software should be used on all ward patients, because high-dependency units will have a system in place for monitoring patients, and it is the ward patients that are more at risk of deterioration.

One specialist commentator pointed out that level 2 patients are more likely to have invasive monitoring, which may reduce the usefulness of a score calculated using non-invasive measurements.

Equality considerations

NICE is committed to promoting equality and eliminating unlawful discrimination. In producing guidance, NICE aims to comply fully with all legal obligations to:

- promote race and disability equality and equality of opportunity between men and women
- eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

Older age is associated with higher clinical risk. Physiological parameters are modified during pregnancy and therefore the VSI may be less reliable when used for pregnant patients. Age and pregnancy are protected characteristics under the Equality Act (2010).

Evidence review

Clinical and technical evidence

Regulatory bodies

A search of the Medicines and Healthcare Products Regulatory Agency website revealed that no manufacturer Field Safety Notices or Medical Device Alerts for this device. No reports of adverse events were identified from a search of the US Food and Drug Administration (FDA) database: Manufacturer and User Device Facility Experience (MAUDE).

Clinical evidence

Two fully published studies on the Visensia system and 4 studies that were available only as abstracts are summarised in this briefing. The fully published studies were 1 prospective, single-centre, before-and-after study (Hravnak et al. 2011) and 1 randomised controlled trial that included a retrospective assessment of the Visensia alerts (Watkinson et al. 2006).

Two further studies (Tarassenko et al. 2005; Orphanidou et al. 2009) that did not report patient outcomes were excluded from further assessment, as was 1 paper (Hravnak et al. 2008) that was a phase I report of the Hravnak et al. (2011) study. Four other abstracts which presented overlapping results of the Hravnak (2008) and Hravnak et al. (2011) studies were also excluded.

The Hravnak et al. (2011) study (presented in tables 1 and 2) was a prospective, single-centre, before-and-after study based in the US. It used Visensia to analyse data for 4 vital signs: heart rate, respiratory rate, blood pressure and peripheral oxygen saturation. The study assessed whether the VSI (calculated from data for the 4 vital signs) correlated with single-parameter cardio-respiratory instability concern criteria. Specifically, these criteria were a heart rate of <40 or >140 beats/min, a respiratory rate of <8 or >36 breaths/min, systolic blood pressure of <80 or >200 mm Hg, diastolic blood pressure of >110 mm Hg, and peripheral oxygen saturation of <85%. The study also assessed whether nurse response to VSI alerts were associated with a reduction in patient instability. The study had 3 sequential stages. In stage 1 (8 weeks), patients had continuous single-channel monitoring and standard care; the VSI was recorded but not displayed. In stage 2 (16 weeks), the VSI was displayed on the bedside and central monitors and staff were educated on using the software. In stage 3 (8 weeks), staff responded to VSI alerts using a pre-defined process developed for this purpose.

In order to evaluate the impact of VSI alerts, the individual vital signs data were analysed to determine the total time when variables were within the normal physiological range (no instability), and the incidence and duration of any episodes in which the cardio-respiratory instability concern criteria were exceeded for any reason (defined as an instability episode). These instability episodes were further categorised as instability episodes that were physiologically plausible (that is, not a result of minimal exceptions to the concern criteria) and full instability episodes, which were serious, persistent and generally displayed abnormalities across multiple vital signs.

Compared with stage 1, stage 3 (in which staff responded to VSI alerts) showed a statistically significant reduction in the average duration of instability episodes per admission, average duration of physiologically plausible instability episodes per admission, and average number of full instability episodes per admission. There was no statistically significant difference in the other reported instability categories.

The randomised controlled trial by Watkinson et al. (2006; presented in table 3) assessed continuous electronic monitoring of vital signs for reducing the frequency of adverse events in high-risk patients outside of critical care areas compared with standard ward care. BioSign (the previous name for Visensia) was used to record the vital signs of patients in the continuous electronic monitoring. The VSI of the patients in the continuous electronic monitoring group was assessed retrospectively by 2 senior clinicians once patients had completed the study. The software was not used to alert nurses.

Technical problems with the BioSign software prevented recording for the whole monitoring period in 33 (17%) patients. Out of 690 transitions from normal to abnormal physiological activity,

652 were considered true episodes. The development of an abnormal physiological episode into a major event could be predicted using BioSign's recording of vital signs, with a sensitivity of 63% and specificity 52%.

The abstracts by Sen et al. (2009 and 2010a) reported a retrospective analysis of trauma registry data. The registry included 117 patients admitted to a level 1 trauma centre over 6 months. Vital sign data were collected both pre-hospital and from the emergency department and the VSI calculated retrospectively. The study found that, pre-hospital, a VSI over 3 was predictive of patients who needed life-saving interventions (odds ratio 1.8, 95% confidence interval [CI] 1.1–4.2). The VSI had statistically significant likelihood ratios for life-saving interventions including endotracheal intubation, blood transfusion, CPR and use of resuscitation drugs.

The abstract by Sen et al. (2010b) reported a retrospective analysis of trauma registry data on 297 patients admitted to a level 1 trauma centre over 6 months. Pre-hospital VSI data were also calculated. The study found that a pre-hospital VSI of over 3 was predictive of patients who needed life-saving interventions (odds ratio 1.8, 95% CI 1.3–3.4; $p<0.05$).

The abstract by Choukalas et al. (2011) reported a retrospective cohort study in a mixed medical-surgical-cardiac ICU in an urban tertiary-care hospital. It included 20 consecutive patients that had a cardiac arrest needing advanced cardiac life support level (ACLS) care while in hospital. VSI data were calculated at 5-minute intervals for the 20 hours before cardiac arrest. Six of the patients did not need ACLS care. For the remaining 14, the mean lead-time of the VSI alert before cardiac arrest was 15.1 hours. Nurses documented patient instability an average of 9.3 hours before cardiac arrest.

The abstract by Choukalas et al. (2015) reported a retrospective controlled cohort study in an 18-bed ICU in an urban hospital, including 61 patients who had a cardiac arrest while in hospital and 729 controls. VSI data were calculated at 1-minute intervals for the 24 hours before cardiac arrest. The study found that there was no difference in VSI between the 2 groups at the beginning of the observation period, but that it became significantly higher for patients with cardiac arrest starting from 10 hours prior ($p<0.05$). The study used a version of the software without preset alert levels and which is not currently commercially available.

Recent and ongoing studies

No ongoing or in-development trials on the Visensia physiological monitoring system for detection of early clinical deterioration were identified.

Costs and resource consequences

No published evidence on resource consequences was identified. If the Visensia system allowed earlier intervention for deteriorating vital signs, then resources on treatment of complications could be saved. If it were shown to be more sensitive than other alert systems, Visensia could also provide efficiencies to the NHS by reducing the number of false alarms that take up nurses' time. Visensia is used alongside existing methods of vital sign monitoring.

Strengths and limitations of the evidence

Only 2 fully published studies were identified. One (Hravnak et al. 2011) was a prospective, single-centre, before-and-after study and the other (Watkinson et al. 2006) was a retrospective assessment embedded in a randomised controlled trial.

The prospective, single-centre, before-and-after study was based in the USA. All potentially unstable patients who were transferred from ICUs to step-down units for further care were included in the study. The patient population consisted of consecutive patients recruited at different time periods for the 2 phases being compared, and were not randomised. Two physicians blinded to the phases of the study independently scored data for phase 1 and phase 3, limiting potential bias. The results may have been confounded by changes in ward care implemented during phase 2 of the study (such as additional training for nurses and physicians). The improvements attributed to Visensia may also have been due to improvements in patient care introduced during phase 2 of the study.

The study by Watkinson et al. (2006) used Visensia to record vital signs but did not use the VSI to advise patient care during the study. For this reason, the results are limited to a retrospective assessment of the logged data and identification of true abnormal physiological activity. From this study it is not clear if the use of Visensia could have led to a reduction in major events.

The 4 studies published as abstracts provide limited information in terms of study setting, methods, characteristics and results. The information is insufficient to allow judgment of the quality of the evidence in these abstracts.

Relevance to NICE guidance programmes

NICE has issued the following guidance:

- Acutely ill patients in hospital (2007) NICE guideline CG50. Date for review: December 2015

References

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Search strategy and evidence selection

Search strategy

1. Databases were searched from inception to January 2015 including MEDLINE(R) In-Process & Other Non-Indexed Citations and MEDLINE(R) (via Ovid); Embase (via OVID); Cochrane Library; CAB Abstracts; Web of Science Science Citation Index. The keywords visensia and biosign were used for the searches.

2. The internet was searched using the above keywords.

3. ClinicalTrials.gov, WHO ICTRP, and Current Controlled Trials were also searched for ongoing trials.

4. Information provided by the manufacturer was thoroughly checked for relevant studies. Information provided by the manufacturer in supporting this briefing was checked to identify any further information.

5. The manufacturer's website was thoroughly investigated.

Evidence selection

The inclusion criteria were as follows:

Patients: adult patients in level 1 and level 2 care for whom multi-parameter patient monitoring has been routine.

Intervention: Visensia, a physiological monitoring system for detecting early clinical patient deterioration in vital signs.

Comparator: non-Visensia monitoring

Outcomes: any relevant efficacy and safety clinical outcomes, including but not limited to:

- Reduction in patient instability
- Nurse response to alert for patient attention and time to alert
- Clinical workload change
- Prevention of major adverse events e.g. cardiac arrest, unscheduled admission to ICU, or death
- Acute change in treatment or care level
- Unscheduled visit by clinical staff
- Emergency surgical procedure
- In-hospital mortality
- Length of hospital stay
- Sensitivity
- Specificity
- Positive predictive value
- Negative predictive value

Study design: for effectiveness any controlled study will be included; for safety aspect of the device, any controlled study, non-controlled study and case report will be included. Systematic reviews and

meta-analyses will be used for identifying relevant primary studies only. Proof of concept and non-English language studies will be excluded.

Appendix

Contents

Data tables

Table 1 Overview of the Hravnak et al. (2011) study

Study component	Description
Objectives/ hypotheses	To assess whether using an integrated monitoring system (Visensia) that continuously amalgamates 4 single monitoring parameters input (including HR, RR, BP, and SpO2) into an instability index value (INDEX), correlates with a single-parameter cardio-respiratory instability concern criterion, and whether nurse response to INDEX alert for patient attention is associated with instability reduction.

Study design	Prospective, single-centre, before-and-after evaluation in sequential 8-, 16-, and 8-week phases (phase 1, phase 2, and phase 3 respectively), with a total project duration of 32 weeks (November 2006 to August 2007). Phase 1: patients received continuous single-channel monitoring (heart rate, respiratory rate, blood pressure, and peripheral oxygen saturation) and standard care; INDEX background was recorded but not displayed. Phase 2: INDEX was background-recorded; members of staff were educated on use. Phase 3: staff used a clinical response algorithm for INDEX alerts. All phase 1 and 3 data were scored blindly off-line and independent of phase. The best balance between cardio-respiratory instability concern criteria and the INDEX threshold was at a sensitivity of 70.5% and specificity of 71% when the INDEX alert threshold was set at ≥3.2. This SDU-specific INDEX alert threshold was sensitive and specific to detect cardio-respiratory instability as defined by single-parameter vital sign criteria (i.e. an HR of <40 or >140 beats/min, an RR of <8 or >36 breaths/min, systolic BP of <80 or >200 mm Hg, diastolic BP of >110 mm Hg, and SpO_2 of <85%) for instability concern, which also served as medical emergency treatment activation triggers. The ≥3.2 INDEX value was used for staff alert to an instability state in phase 3.
Setting	A 24-bed trauma step-down unit in a single urban tertiary care centre in the USA.
Inclusion/ exclusion criteria	Not reported. Subjects were all monitored patients.

Outcomes	The correlation between the monitoring system INDEX and instability states according to the University of Pittsburgh Medical Centre cardio-respiratory instability concern criterion (INSTABILITY); Comparison of phase 1 and 3: the mean numbers of times admissions in each phase experienced an episode of instability and mean durations of times admissions in each phase were in unstable states the number of admissions experiencing at least one episode of an instability state the cumulative number of occurrences in which patients were above the thresholds of instability concern criteria for each phase the cumulative duration of time in which patients were above the thresholds instability for patients who experienced it in phase 1 and phase 3. The categorisation of instability was performed independently by 2 critical care medicine physician investigators experienced in cardio-respiratory instability with the data blinded to data phase and using only the parsimonious definitions.
Statistical methods	Analyses were performed by using Student's *t* tests, chi-square or Fisher exact comparisons, and Spearman's rho correlation. Significance corresponded to $p<0.05$.
Patients included	All potentially unstable patients who were transferred out of intensive care units ICUs to step-down units for further care, including 326 patients in phase 1 and 306 patients in phase 3 during these intervals.
Results [a]	Compared with phase 1, phase 3 had statistically significant reduction in average duration of any episode of instability ($INSTABILITY_{hit}$) per admission, average duration of physiologically plausible instability ($INSTABILITY_{min}$) per admission, and average number of full instability ($INSTABILITY_{full}$) per admission. There was no statistically significant difference between the phases in the other reported INSTABILITY categories.
Authors' conclusions	The integrated monitoring system INDEX correlated significantly with cardio-respiratory instability concern criteria, usually occurred before overt instability, and was associated with decreased cardio-respiratory instability concern criteria when coupled with a nursing alert in step-down unit patients.

Abbreviations: BP, blood pressure; CI, confidence interval; ICUs, Intensive care units; HR, heart rate; n, number of patients; OR, odds ratio; RR, respiratory rate; SpO_2, peripheral oxygen saturation.

[a] INSTABILITY, vital sign monitoring parameters were beyond instability-concern thresholds; $_{hit}$, vital-sign-monitoring parameters across instability concern thresholds for any cause, including artifact; $_{min}$, subset of $_{hit}$ for instability that was physiologically real (i.e. nonartifactual) even if transient; $_{full}$, subset of min for instability judged as serious and persistent and in need of intervention.

Table 2 Summary of results from the Hravnak et al. (2011) study

	Phase 3 (Visensia)	Phase 1 (usual care)	Analysis
Number of patients monitored	n=306	n=326	
Efficacy [a]	n=303	n=319	
Selected outcomes			
Average number of INSTABILITY$_{hit}$ per admission (mean±SD) [b]	2.5±5	4.0±9	p=0.068
Average duration of INSTABILITY$_{hit}$ per admission (minutes, mean±SD) [b]	25±57	57±129	p=0.007
Average number of INSTABILITY$_{min}$ per admission (mean±SD) [b]	1.5±4	2.2±6	p=0.898
Average duration of INSTABILITY$_{min}$ per admission (minutes, mean±SD) [b]	13±41	28±76	p=0.018
Average number of INSTABILITY$_{full}$ per admission (mean±SD) [b]	0.4±1.5	0.9±3	p=0.033
Average duration of INSTABILITY$_{full}$ per admission (minutes, mean±SD) [b]	7±27	16±53	p=0.050
Number of admissions experiencing at least one INSTABILITY$_{min}$ episode (n, %) [b]	158 (51%)	173 (52%)	p=0.57

Number of admissions experiencing at least one $INSTABILITY_{hit}$ episode (n, %) [b]	102 (33%)	114 (35%)	p=0.565
Number of admissions experiencing at least one $INSTABILITY_{full}$ episode (n, %) [b]	48 (15%)	68 (20%)	p=0.09
Death (n, %)	3 (1%)	7 (2%)	Not reported
Unexpected death	0	6	Not reported

Abbreviations: CCU, critical care unit; CI, confidence interval; ICU, intensive care unit; ITT, intention to treat; NR, not reported; n, number of patients or events; RR, relative risk.

[a] Total number of admissions alive at discharge.

[b] INSTABILITY, vital sign monitoring parameters were beyond instability-concern thresholds; $_{hit}$, vital-sign-monitoring parameters across instability concern thresholds for any cause, including artifact; $_{min}$, subset of hit for instability that was physiologically real (i.e., nonartifactual) even if transient; $_{full}$, subset of min for instability judged as serious and persistent and in need of intervention.

Table 3 Overview of the Watkinson et al. (2006) study

Study component	Description
Objectives/ hypotheses	To assess whether mandated electronic vital signs monitoring reduced the frequency of adverse events in high risk medical and surgical patients outside of critical care areas, compared with that in a control group receiving usual ward care.
Study design	Randomised controlled trial. Ward and study staff were not blinded to the intervention. For the group with mandated electronic vital signs monitoring, BioSign was only used to record vital signs data which was evaluated retrospectively. True episodes of severe physiological abnormalities were determined by 2 senior clinicians.
Setting	Medical or surgical acute ward in John Radcliffe Hospital, Oxford, UK; between September 2003 and September 2005. Follow-up: from recruitment for 72 hours or until the patient or caring nurse requested removal.

Inclusion/ exclusion criteria	Adult 'high risk' patients admitted as medical or surgical emergencies or undergoing major elective surgery at the study hospital between September 2003 and September 2005 were recruited. 'High risk' patients were those where the expected rate of complications (including death) from the primary illness or procedure exceeded 5% in published case series, the control groups of trials, or local audit data. Patients scheduled to receive their initial postoperative care on an intensive care unit were included but were not assigned until they were discharged to the acute ward. Patients were not included if they were expected to be sufficiently mobile to leave the bed space unaided within 72 hours of operation or recruitment.
Primary outcomes	Proportion of patients experiencing a major event (urgent staff calls, a change to a higher care level, cardiac arrest, or death) in 96 hours following randomisation.
Statistical methods	The sample size was estimated to be 405 to detect a clinical significant difference in event rates of 15%. Chi-squared tests were used to determine the statistical significance of any difference in proportions of patients with major adverse events.
Patients included	Patients admitted as medical or surgical emergencies or undergoing major elective surgery (n=405).
Results	Patients with a major event by 96 hours: 113 (56%) monitored patients compared with 116 (58%) control patients; OR 0.94 (95% CI 0.63–1.40), p=0.76. Out of 690 transitions from normal to abnormal physiological activity, 652 were considered true episodes. There were technical problems with the BioSign device that prevented recording for the whole monitoring period in 33 (17%) patients. The patients with severe abnormalities that would have caused an alert by the BioSign device were more likely to have a major event (sensitivity 63%, specificity 52%).
Authors' conclusions	Mandated electronic vital signs monitoring in high risk medical and surgical patients had no effect on adverse events or mortality.
Abbreviations: CI, confidence interval; OR, odds ratio; n, number of patients.	

Table 4 Summary of relevant abstracts

ID	Design/method	Findings

Sen et al. 2009; Sen et al. 2010a [a]	Retrospective analysis of a trauma registry data. N=117 patients admitted to a level 1 trauma centre over a 6-month period. Vital signs were obtained from the pre-hospital run-sheets and upon arrival to the emergency department. An initial pre-hospital VSI and an emergency department VSI were calculated. Pre-hospital life-saving interventions (LSIs) and those carried out within 6 hours of arrival to the trauma centre (fluid bolus, CPR drugs, intubation, transfusion etc.) were considered outcome variables.	Univariate analysis: pre-hospital VSI >3 was predictive of trauma patients who needed LSI (OR1.8, 95% CI 1.1–4.2). Multivariate analysis: VSI had significant likelihood ratios for life-saving interventions including endotracheal intubation, blood transfusion, CPR and use of resuscitation drugs ($p<0.001$). The model had an area under ROC of 0.76 in discriminant analysis. VSI outperformed other independent variables like heart rate, blood pressure, injury severity score and base deficit.
Sen et al. 2010b [a]	Retrospective analysis of a trauma registry data. N=297 patients admitted to a level 1 trauma centre over a 6-month period. Vital signs were obtained from the pre-hospital run-sheets. Pre-hospital VSI was calculated based on the vital signs in a blinded manner. Pre-hospital life-saving interventions and those carried out within 6 hours of arrival to the trauma centre (CPR, resuscitative drugs, intubation, blood transfusion, chest tubes, emergency laparotomy etc) were considered outcome variables.	Multivariate analysis: pre-hospital VSI >3 was predictive of trauma patients who needed LSI after arrival to a trauma centre in the (OR1.8, 95% CI1.3–3.4; $p<0.05$). The model had an area under ROC of 0.79 in discriminant analysis. VSI outperformed other independent variables like heart rate, systolic blood pressure, oxygen saturation and Glasgow Coma Scale.

Choukalas et al. 2011	A cohort study of the 20 most recent consecutive patients suffering cardiac arrest requiring ACLS level care, in a mixed medical-surgical-cardiac ICU in a large, urban, tertiary-care, academic teaching hospital. Data were collected sufficient to calculate a VSI at 5-minute intervals for the 20 hours prior to cardiac arrest. The primary outcome measure was the lead-time between the first episode of instability (defined as a VSI≥3.2) and cardiac arrest. Patient records were also reviewed to identify the first point of nursing documentation of patient instability within the 20 hours prior to arrest.	Of the 20 most recent cardiac arrests, 6 were excluded because they did not require ACLS care. Of the remaining 14 arrests, 9 were attributed to cardiac causes and the remainder respiratory. Of the 14 arrests 8 were fatal. The mean lead-time of the VSI alert prior to arrest was 15.1 (SD=6.6) hours. Nurses documented instability an average of 9.3 (SD=7.1) hours prior to arrest.
Choukalas et al. 2015	A controlled cohort study in a large, urban, academic teaching hospital with 18 ICU beds. Data were extracted to calculate a VSI at one-minute intervals for the 24 hours prior to arrest for patients undergoing cardiac arrest in the ICU between 2005 and 2011 as identified by a hospital quality improvement database. Control patients were all patients in the ICU during the 24 hour periods which defined cases. Hourly average VSI were calculated and compared between cases and controls using mixed effects linear models with a random effect for each subject.	Sixty one cases and 729 controls were included in the analysis. Cases were more ill than controls in that a greater proportion of them had co-morbidities such as congestive heart failure and recent myocardial infarction. VSI showed no difference between the 2 groups at the beginning of the observation period, but became significantly higher for cases starting at 10 hours prior to arrest ($p<0.05$). VSI for cases continued to rise and separate from that of controls consistently leading up to the end of the observation period, when cases experienced cardiac arrest. The averaged vital signs did not show trends or changes in the hours leading up to the eventual cardiac arrest.

Abbreviations: ACLS, advanced cardiac life support; CI, confidence interval; CPR, cardiopulmonary resuscitation; ICU, intensive care unit; LSI, life-saving intervention; n, number of patients; ROC, receiver-operating characteristic; RR, relative risk; SD, standard deviation; VSI, Visensia Safety Index.

[a] Both retrospective studies were conducted by the same authors analysing registry data on Visensia index for the prediction of life-saving interventions in pre-hospital trauma patients. It was unclear whether the Sen et al. 2010b study combines data from the Sen et al. 2009 and Sen et al. 2010a studies.

About this briefing

Medtech innovation briefings summarise the published evidence and information available for individual medical technologies. The briefings provide information to aid local decision-making by clinicians, managers and procurement professionals.

Medtech innovation briefings aim to present information and critically review the strengths and weaknesses of the relevant evidence, but contain no recommendations and **are not formal NICE guidance**.

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Declarations of interest

No relevant interests were declared.

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